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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,401	11/21/2005	Hiroshi Tsuchita	Q88294	1465

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2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
TSAY, MARSHA M	
ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
06/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SUGHRUE265550@SUGHRUE.COM
USPTO@SUGHRUE.COM
PPROCESSING@SUGHRUE.COM

Office Action Summary	Application No.	Applicant(s)	
	10/537,401	TSUCHITA ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,16,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,16,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This Office action is in response to Applicants' remarks received March 10, 2010.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 2-4, 7-15, 17-19, 22-23 are canceled. Claims 1, 5-6, 16, 20-21 are currently under examination.

Priority: The request for priority to JAPAN 2002-350200, filed December 2, 2002, is acknowledged. A certified copy of the foreign priority document has been filed in this case on June 2, 2005, and is in a non-English language.

Objections and Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-6, 16, 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantman (US 4687782; IDS; previously cited) in view of Soop et al. (1988 J Appl Physiol 64(6): 2394-2399; previously cited). Brantman discloses a composition consisting essentially of carnitine, isoleucine, leucine, valine, glutamine, and a whey protein, i.e. casein, soy protein, lactalbumin (col. 7 lines 30-50), adapted for use with water as a diet supplement for facilitating the adaptation of skeletal muscle and liver to a program of strenuous exercise. Brantman further

discloses a method of supplementing the diet of an athlete by having the athlete drink a solution consisting essentially of leucine, isoleucine, valine, glutamine, and a whey protein, and having the athlete drink the solution (col. 6 lines 42-53). In col. 4 lines 45-50, Brantman discloses numerical ranges for the amino acids used in the composition: leucine (20-45 parts), isoleucine (15-40 parts), valine (15-40 parts), glutamine (10-30 parts), carnitine (0.3-2.0 parts), wherein the relative proportions of the amino acids are preferably within 20% of the recited ranges (col. 5 lines 20-25). It should also be noted that Brantman discloses that carnitine is an endogenous amino acid (col. 3 lines 55-63). Further, one of ordinary skill can see that out of all the amino acids used in said composition, carnitine is present in the smallest amount, i.e. 0.3 -2.0 g (col. 4 lines 45-50). Brantman further discloses that its composition is intended to provide the best metabolic milieu to permit and encourage protein synthesis in skeletal muscle (col. 4 lines 17-20). Brantman does not specifically teach a composition consisting of leucine, isoleucine, valine, glutamine, and a whey protein.

Soop et al. disclose the influence of carnitine supplementation on muscle substrate and carnitine metabolism during exercise. Soop et al. disclose that adequate muscle carnitine levels are maintained during exercise and that carnitine supplementation has no substantial effect on skeletal muscle metabolism under normal physiological conditions (p. 2399).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Brantman and formulate a composition consisting of isoleucine, leucine, valine, glutamine, and a whey protein, i.e. casein (claim 1, 5-6) and administer said composition to an athlete (claim 16, 20-21). One of ordinary skill would be motivated to administer said composition to an athlete and expect it to be successful in

improving fatigue during exercise because Brantman teaches a composition consisting essentially of the branched amino acids, i.e. isoleucine, leucine, leucine, valine, glutamine, and a whey protein, which can be administered to promote muscle adaptation to strenuous exercise in a person. The motivation to exclude carnitine from said composition is suggested by Soop et al. which disclose that carnitine supplementation has no substantial effect on skeletal muscle metabolism, therefore, it would be reasonable for one of ordinary skill to exclude carnitine from the composition of Brantman since said composition of Brantman is intended to provide an optimum environment to permit and encourage protein synthesis in skeletal muscle and exogenous carnitine does not appear to have a substantial effect on skeletal muscle metabolism.

In their remarks received March 10, 2010, Applicants assert that (1) Although Soop *et al.* teach that camitine supplementation has no substantial effect on skeletal muscle metabolism under normal physiological conditions, Soop *et al.* 's study relates to the single use of carnitine and its effect on skeletal muscle metabolism under normal physiological conditions. In contrast, Brantman teaches that the critical feature of his invention is the specific application of certain amino acids (camitine, glutamine, isoleucine, leucine and valine) which exert beneficial effects on the metabolism (especially protein synthesis) of skeletal muscle (col. 1, lines 11-14 and 57-59). Therefore, Soop *et al.* is not sufficient to provide motivation to one skilled in the art to omit cartinine from the composition of Brantman. Further, Brantman recognizes that camitine metabolism increases during exercise training (col. 3, lines 64-65) and teaches that "the present invention employs camitine to optimize skeletal muscle function in relation to oxidation of fatty acids for calories; to the oxidation of BAA for the effects summarized above; and to enhance the

removal of toxic ammonia" (col. 4, lines 8-12). That is, Brantman employs camitine with other specific amino acids to promote muscle adaptation to strenuous exercise. (2) Accordingly, omission of carnitine from the composition of Brantman would render it unsatisfactory for its intended purpose; relevant law holds that if a proposed modification would render a prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon,* 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Brantman expressly discloses that the intended purpose of the composition is to provide "a dietary supplement which provides the best metabolic milieu to permit and encourage protein synthesis in skeletal muscle and in liver... [and that] the objects of the invention are realized by a careful selection of specific amino acids to be added to whole protein and other nutrients, so as to achieve a diet which is enriched with specific amino acids (carnitine, glutamine, isoleucine, leucine and valine), in order to maximize protein synthesis in skeletal muscle" (col. 4, lines 18-30). Therefore, by omitting camitine, the composition is rendered unsatisfactory as a dietary supplement which provides the *best metabolic milieu* to permit and encourage protein synthesis in skeletal muscle and in liver, given that Brantman teaches carnitine as being critical for this purpose. Furthermore, the composition defined in the claims of the instant application is patentable over Brantman from the fact that the claimed composition retains and improves the desired function even carnitine, which was an essential element of Brantman's composition, is omitted.

Applicant's arguments have been fully considered but they are not persuasive.

(1) Response: It should be noted that MPEP 2144.04 states that the omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu*, 10

USPQ 2031 (Bd. Pat. App. & Inter. 1989) (Claims at issue were directed to a method for inhibiting corrosion on metal surfaces using a composition consisting of epoxy resin, petroleum sulfonate, and hydrocarbon diluent. The claims were rejected over a primary reference which disclosed an anticorrosion composition of epoxy resin, hydrocarbon diluent, and polybasic acid salts wherein said salts were taught to be beneficial when employed in a freshwater environment, in view of secondary references which clearly suggested the addition of petroleum sulfonate to corrosion inhibiting compositions. The Board affirmed the rejection, holding that it would have been obvious to omit the polybasic acid salts of the primary reference where the function attributed to such salt is not desired or required, such as in compositions for providing corrosion resistance in environments which do not encounter fresh water.). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965) (Omission of additional framework and axle which served to increase the cargo carrying capacity of prior art mobile fluid carrying unit would have been obvious if this feature was not desired.); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (deleting a prior art switch member and thereby eliminating its function was an obvious expedient).

In this instance, Brantman (the primary 103a reference) discloses a composition consisting essentially of carnitine, isoleucine, leucine, valine, glutamine, and a whey protein, i.e. casein, soy protein, lactalbumin (col. 7 lines 30-50), adapted for use with water as a diet supplement for facilitating the adaptation of skeletal muscle and liver to a program of strenuous exercise. Therefore, the intended purpose of said composition is to maximize protein synthesis in skeletal muscle in order to promote muscle adaptation to strenuous exercise. However, since Soop et al. disclose that adequate muscle carnitine levels are maintained during exercise and that

carnitine supplementation has no substantial effect on skeletal muscle metabolism under normal physiological conditions, it would be reasonable for one of ordinary skill to know that the exclusion of carnitine from said composition of Brantman would be obvious since the function of said carnitine is not desired, i.e. adequate carnitine levels are maintained during exercise.

Additionally, one of ordinary skill would know that excluding carnitine in said composition of Brantman would be cost effective because the exclusion of an unnecessary component would have economic advantages, i.e. it would cost less to manufacture a composition without an additional ingredient. One of ordinary skill would be motivated to utilize any combination of one or more of the composition ingredients of Brantman (such as leucine alone, leucine and isoleucine, leucine, isoleucine and valine, etc.) in order to prepare an effective composition for muscle treatment that is cost effective and it is for this reasons that the instant invention is obvious.

(2) Response: Brantman discloses that the carnitine employed in said composition is used for the purpose of oxidizing branched amino acids (i.e. the branched amino acids glutamine, isoleucine, leucine and valine that are in said composition) in muscle and to enhance the removal of toxic ammonia (col. 4 lines 3-13). Therefore, since Soop et al. disclose that adequate muscle carnitine levels are maintained during exercise, then there would still be an appropriate level of carnitine present in the body when said composition is administered during exercise, so that the branched amino acids will be oxidized and toxic ammonia will be removed.

Therefore, it would be reasonable for one of ordinary skill to want to exclude carnitine from said composition of Brantman since the function of said carnitine is not desired and said

composition of Brantman would still have the same intended purpose without carnitine being present.

At least for these reasons, the claims remain rejected under 35 U.S.C. 103(a).

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

June 1, 2010

M. Tsay
Art Unit 1656